



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0212]

Tobacco Product Analysis; Scientific Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products is announcing a scientific workshop to solicit feedback on analysis of tobacco products. The analyses of tobacco products often involve tobacco reference products, which are used primarily as controls to ensure that the results of the analyses are reliable and accurate. This scientific workshop will focus on understanding how tobacco reference products are used and the testing methods used to analyze tobacco products. FDA will invite speakers to address scientific and technical matters relating to the testing of tobacco reference products and the analytical methods used to measure constituent levels in tobacco products and smoke. FDA is also opening a public docket to receive comments on these topics.

Dates and Time: The public workshop will be held on April 11, 2012, from 8:30 a.m. to 5:30 p.m., and on April 12, 2012, from 8:30 a.m. to 4 p.m. Individuals who wish to attend the public workshop must register by close of business on March 30, 2012. Submit either electronic or written comments to the docket by May 11, 2012.

Location: The public workshop will be held at 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373.

Contact Person: Anuja Patel, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 1-877-287-1373, FAX: 240-276-3761, email: [workshop.CTPOS@fda.hhs.gov](mailto:workshop.CTPOS@fda.hhs.gov).

Registration to Attend the Workshop and Requests for Oral Presentations: If you wish to attend the workshop or make an oral presentation at the workshop, please email your registration to [workshop.CTPOS@fda.hhs.gov](mailto:workshop.CTPOS@fda.hhs.gov) by close of business on March 30, 2012. Those without email access may register by contacting Anuja Patel (see Contact Person). Please provide contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

There will be opportunities for audience participation at this workshop. FDA has included topics for comment in section II of this document. FDA will do its best to accommodate requests to speak during the workshop sessions, although questions from the audience may be limited. In addition, we strongly encourage submitting comments to the docket (see Comments).

If you need special accommodations because of disability, please contact Anuja Patel (see Contact Person) at least 7 days before the workshop.

Comments: Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments on any of the topics for discussion in section II of this document by May 11, 2012. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Workshop Topics

The purpose of this scientific workshop is to obtain information and comments from appropriate scientific experts on analysis of tobacco products. Such experts could include, but are not limited to, scientists from academia, tobacco product manufacturers, and contract testing laboratories. The workshop will include scientific experts who will present scientific and technical information on testing of tobacco reference products for different types of tobacco products. The types of tobacco reference products to be discussed include, but are not limited to, smoked tobacco products, smokeless tobacco products, and other tobacco products not classified as either smoked or smokeless products. FDA would like to discuss how the tobacco reference products are used for testing purposes to ensure accuracy of analysis of tobacco products. Tobacco reference products are analyzed alongside test tobacco products (i.e., during every step of the analysis). Tobacco reference products are intended for use during analysis of tobacco products and are not intended for human consumption. Tobacco reference products are finished tobacco products and are distinct from internal reference standards, which are chemicals or

mixtures of chemicals. Internal reference standards are used during only certain steps of the analysis of test tobacco products (e.g., when running samples).

The scientific workshop will include discussion of analytical methods for measuring certain constituents in tobacco products and smoke. The aspects of analytical methods that will be discussed include extraction, separation, and detection methods. For example, FDA would like to get input from scientific experts on how tobacco-specific nitrosamines (TSNAs) are extracted from smokeless tobacco products and cigarette smoke particulate matter and what instrumentation (e.g., gas chromatography-mass spectrometry) is used to measure the levels of TSNAs.

FDA is interested in receiving substantive scientific input at the workshop and in the docket. The input from the scientific workshop may assist us in developing future scientific workshops regarding analysis of tobacco products.

## II. Workshop Topics for Discussion

FDA will explore all or some of the following topics during this scientific workshop:

### 1. Availability, manufacture, and characterization of tobacco reference products

A. Discuss the current availability of tobacco reference products for different types of tobacco products and what new products would be beneficial.

B. Discuss the types and blends of tobacco used in reference products. What additional blends or other product characteristics should be most applicable for all products, both those currently and those expected to be introduced on the market?

C. Describe the storage conditions for tobacco reference products to ensure shelf life. Please provide data that shows product changes under different storage conditions.

What storage conditions are most critical in maintaining product integrity? What precautions should be taken to ensure product integrity?

D. Discuss the stability of the tobacco reference products and methods used to verify product stability. What precautions are taken to maximize product stability? What product characteristics are most stable and which are least stable?

E. Describe any ongoing work to develop tobacco reference products that are not currently available for laboratory use. Discuss considerations made when determining the need and developing a new tobacco reference product.

## 2. Uses of reference products during analysis of tobacco products

A. Discuss the physical and chemical measurements performed on tobacco reference products during analysis of tobacco products. Please provide data. How are reference products used in research and manufacturing?

B. Discuss the advantages and disadvantages of using one or multiple tobacco reference products when performing analysis of a given tobacco product type.

C. Discuss the procedures used when transitioning from using one tobacco reference product to using another tobacco reference product for the same tobacco product type to ensure long-term consistency in findings.

D. Discuss the policies, procedures, and frequency related to discarding data for reference products due to unacceptable analytical results.

E. Discuss the policies and procedures used in research and manufacturing when no tobacco reference product is available for a specific type of tobacco product. Is there a policy of using a similar product when the specific reference product is not available? What considerations are applied?

F. Describe characteristics of a tobacco reference product that would provide advantages or disadvantages over another.

3. Variability observed in measurements of tobacco reference products

A. Provide data that address the variability that exists in the chemical measures of a reference product analyzed within the same laboratory. Describe how measures compare between different laboratories.

B. Provide data that address the variability that exists in the physical measures of a reference product analyzed within the same laboratory. Describe how measures compare between different laboratories.

C. Describe any other factors that affect the variability of a tobacco reference product when analyzed using analytical measurements.

D. Discuss the procedures or methods that have been used or may be used to reduce the tobacco reference product variability.

4. Methods suitable for measuring the following in smoked and smokeless tobacco products: pH, tobacco-specific nitrosamines, polycyclic aromatic hydrocarbons, carbon monoxide, and metals

A. Discuss the sample preparation or extraction methods for measuring the analytes.

B. Discuss the analytical methodologies (gas chromatography, thermal energy analyzer, liquid chromatography, mass spectrometry, etc.) used for quantifying analytes.

C. Discuss the statistical or other mathematical procedures for quantification.

D. Discuss the availability and use of internal reference standards to quantify the analytes.

E. Discuss the approaches and testing methods which are intended to combine measuring of multiple analytes within the same class of constituents into a single analysis. Particularly discuss the benefits in reference to sample throughput and the loss in terms of sensitivity, selectivity, or other analytical terms of reference.

F. Discuss the approaches and testing methods which are intended to measure analytes across different classes of constituents. Particularly discuss the benefits in reference to sample throughput and the loss in terms of sensitivity, selectivity, or other analytical terms of reference.

### III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: March 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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